VISTARIL®
(hydroxyzine pamoate)
Capsules and
Oral Suspension

DESCRIPTION
Hydroxyzine pamoate is designated chemically as 1-(p-chlorobenzhydryl) 4- [2- (2-hydroxyethoxy) ethyl] diethylenediamine salt of 1,1'- methylene bis (2 hydroxy-3-naphthalene carboxylic acid).

Inert ingredients for the capsule formulations are: hard gelatin capsules (which may contain Yellow 10, Green 3, Yellow 6, Red 33, and other inert ingredients); magnesium stearate; sodium lauryl sulfate; starch; sucrose.

Inert ingredients for the oral suspension formulation are: carboxymethylcellulose sodium; lemon flavor; propylene glycol; sorbic acid; sorbitol solution; water.

CLINICAL PHARMACOLOGY
Vistaril® (hydroxyzine pamoate) is unrelated chemically to the phenothiazines, reserpine, meprobamate, or the benzodiazepines.

Vistaril is not a cortical depressant, but its action may be due to a suppression of activity in certain key regions of the subcortical area of the central nervous system. Primary skeletal muscle relaxation has been demonstrated experimentally. Bronchodilator activity, and antihistaminic and analgesic effects have been demonstrated experimentally and confirmed clinically. An antiemetic effect, both by the apomorphine test and the veriloid test, has been demonstrated. Pharmacological and clinical studies indicate that hydroxyzine in therapeutic dosage does not increase gastric secretion or acidity and in most cases has mild antisecretory activity. Hydroxyzine is rapidly absorbed from the gastrointestinal tract and Vistaril's clinical effects are usually noted within 15 to 30 minutes after oral administration.

INDICATIONS
For symptomatic relief of anxiety and tension associated with psychoneurosis and as an adjunct in organic disease states in which anxiety is manifested.

Useful in the management of pruritus due to allergic conditions such as chronic urticaria and atopic and contact dermatoses, and in histamine-mediated pruritus.

As a sedative when used as premedication and following general anesthesia, **Hydroxyzine may potentiate meperidine (Demerol®) and barbiturates,** so their use in pre-anesthetic adjunctive therapy should be modified on an individual basis. Atropine and other belladonna alkaloids are not affected by the drug. Hydroxyzine is not known to interfere with the action of digitalis in any way and it may be used concurrently with this agent.

The effectiveness of hydroxyzine as an antianxiety agent for long-term use, that is, more than 4 months, has not been assessed by systematic clinical studies. The

physician should reassess periodically the usefulness of the drug for the individual patient.

CONTRAINDICATIONS

Hydroxyzine, when administered to the pregnant mouse, rat, and rabbit, induced fetal abnormalities in the rat and mouse at doses substantially above the human therapeutic range. Clinical data in human beings are inadequate to establish safety in early pregnancy. Until such data are available, hydroxyzine is contraindicated in early pregnancy.

Hydroxyzine pamoate is contraindicated for patients who have shown a previous hypersensitivity to it.

WARNINGS

Nursing Mothers: It is not known whether this drug is excreted in human milk. Since many drugs are so excreted, hydroxyzine should not be given to nursing mothers.

PRECAUTIONS

THE POTENTIATING ACTION OF HYDROXYZINE MUST BE CONSIDERED WHEN THE DRUG IS USED IN CONJUNCTION WITH CENTRAL NERVOUS SYSTEM DEPRESSANTS SUCH AS NARCOTICS, NON-NARCOTIC ANALGESICS AND BARBITURATES. Therefore, when central nervous system depressants are administered concomitantly with hydroxyzine, their dosage should be reduced. Since drowsiness may occur with use of the drug, patients should be warned of this possibility and cautioned against driving a car or operating dangerous machinery while taking Vistaril (hydroxyzine pamoate). Patients should be advised against the simultaneous use of other CNS depressant drugs, and cautioned that the effect of alcohol may be increased.

Geriatric Use: A determination has not been made whether controlled clinical studies of VISTARIL included sufficient numbers of subjects aged 65 and over to define a difference in response from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

The extent of renal excretion of VISTARIL has not been determined. Because elderly patients are more likely to have decreased renal function, care should be taken is dose selections.

Sedating drugs may cause confusion and over sedation in the elderly; elderly patients generally should be started on low doses of VISTARIL and observed closely.

ADVERSE REACTIONS

Side effects reported with the administration of Vistaril are usually mild and transitory in nature.

Anticholinergic: Dry mouth.

Central Nervous System: Drowsiness is usually transitory and may disappear in a few days of continued therapy or upon reduction of the dose. Involuntary motor activity, including rare instances of tremor and convulsions, has been reported, usually with doses considerably higher than those recommended. Clinically significant respiratory depression has not been reported at recommended doses.

OVERDOSAGE

The most common manifestation of overdosage of Vistaril is hypersedation. As in the management of overdosage with any drug, it should be borne in mind that multiple agents may have been taken.

If vomiting has not occurred spontaneously, it should be induced. Immediate gastric lavage is also recommended. General supportive care, including frequent monitoring of the vital signs and close observation of the patient, is indicated. Hypotension, though unlikely, may be controlled with intravenous fluids and Levophed® (levarterenol) or Aramine® (metaraminol). Do not use epinephrine, as Vistaril counteracts its pressor action. Caffeine and Sodium Benzoate Injection, USP, may be used to counteract central nervous system depressant effects.

There is no specific antidote. It is doubtful that hemodialysis would be of any value in the treatment of overdosage with hydroxyzine. However, if other agents such as barbiturates have been ingested concomitantly, hemodialysis may be indicated. There is no practical method to quantitate hydroxyzine in body fluids or tissue after its ingestion or administration.

DOSAGE

For symptomatic relief of anxiety and tension associated with psychoneurosis and as an adjunct in organic disease states in which anxiety is manifested: in adults, 50-100 mg q.i.d.; children under 6 years, 50 mg daily in divided doses and over 6 years, 50-100 mg daily in divided doses.

For use in the management of pruritus due to allergic conditions such as chronic urticaria and atopic and contact dermatoses, and in histamine-mediated pruritus: in adults, 25 mg t.i.d. or q.i.d.; children under 6 years, 50 mg daily in divided doses and over 6 years, 50-100 mg daily in divided doses.

As a sedative when used as a premedication and following general anesthesia: 50-100 mg in adults, and 0.6 mg/kg in children.

When treatment is initiated by the intramuscular route of administration, subsequent doses may be administered orally.

As with all medications, the dosage should be adjusted according to the patient's response to therapy.

HOW SUPPLIED

Vistaril® Capsules (hydroxyzine pamoate equivalent to hydroxyzine hydrochloride)

25 mg: 100's (NDC 0069-5410-66), 500's (NDC 0069-5410-73),
and Unit Dose (10 × 10's) (NDC 0069-5410-41) two-tone green capsules

50 mg: 100's (NDC 0069-5420-66), 500's (NDC 0069-5420-73),
and Unit Dose (10 × 10's) (NDC 0069-5420-41) green and white capsules

100 mg: 100's (NDC 0069-5430-66), 500's (NDC 0069-5430-73),
and Unit Dose (10 × 10's) (NDC 0069-5430-41) green and gray capsules

Vistaril® Oral Suspension (hydroxyzine pamoate equivalent to 25 mg hydroxyzine hydrochloride per teaspoonful-5 mL): 1 pint (473 mL) bottles (NDC 0069-5440-93) and 4 ounce (120 mL) bottles (NDC 0069-5440-97) in packages of 4.

Shake vigorously until product is completely resuspended.

BIBLIOGRAPHY

Available on request.

VISTARIL®

hydroxyzine hydrochloride

INTRAMUSCULAR SOLUTION

For Intramuscular Use Only

CHEMISTRY

Hydroxyzine hydrochloride is designated chemically as 1-(p-chlorobenzhydryl) 4-[2-(2-hydroxyethoxy) ethyl] piperazine dihydrochloride.

ACTIONS

VISTARIL (hydroxyzine hydrochloride) is unrelated chemically to phenothiazine, reserpine, and meprobamate. Hydroxyzine has demonstrated its clinical effectiveness in the chemotherapeutic aspect of the total management of neuroses and emotional disturbances manifested by anxiety, tension, agitation, apprehension or confusion.

Hydroxyzine has been shown clinically to be a rapid-acting true ataraxic with a wide margin of safety. It induces a calming effect in anxious, tense, psychoneurotic adults and also in anxious, hyperkinetic children without impairing mental alertness. It is not a cortical depressant, but its action may be due to a suppression of activity in certain key regions of the subcortical area of the central nervous system.

Primary skeletal muscle relaxation has been demonstrated experimentally.

Hydroxyzine has been shown experimentally to have antispasmodic properties, apparently mediated through interference with the mechanism that responds to spasmogenic agents such as serotonin, acetylcholine, and histamine.

Antihistaminic effects have been demonstrated experimentally and confirmed clinically.

An antiemetic effect, both by the apomorphine test and the veriloid test, has been demonstrated. Pharmacological and clinical studies indicate that hydroxyzine in therapeutic dosage does not increase gastric secretion or acidity and in most cases provides mild antisecretory benefits.

INDICATIONS

The total management of anxiety, tension, and psychomotor agitation in conditions of emotional stress requires in most instances a combined approach of psychotherapy and chemotherapy. Hydroxyzine has been found to be particularly useful for this latter phase of therapy in its ability to render the disturbed patient more amenable to psychotherapy in long term treatment of the psychoneurotic and psychotic, although it should not be used as the sole treatment of psychosis or of clearly demonstrated cases of depression.

Hydroxyzine is also useful in alleviating the manifestations of anxiety and tension as in the preparation for dental procedures and in acute emotional problems. It has also been recommended for the management of anxiety associated with organic disturbances and

as adjunctive therapy in alcoholism and allergic conditions with strong emotional overlay, such as in asthma, chronic urticaria, and pruritus.

VISTARIL (hydroxyzine hydrochloride) Intramuscular Solution is useful in treating the following types of patients when intramuscular administration is indicated:

1. The acutely disturbed or hysterical patient.
2. The acute or chronic alcoholic with anxiety withdrawal symptoms or delirium tremens.
3. As pre- and postoperative and pre- and postpartum adjunctive medication to permit reduction in narcotic dosage, allay anxiety and control emesis.

VISTARIL (hydroxyzine hydrochloride) has also demonstrated effectiveness in controlling nausea and vomiting, excluding nausea and vomiting of pregnancy. (See Contraindications .)

In prepartum states, the reduction in narcotic requirement effected by hydroxyzine is of particular benefit to both mother and neonate.

Hydroxyzine benefits the cardiac patient by its ability to allay the associated anxiety and apprehension attendant to certain types of heart disease. Hydroxyzine is not known to interfere with the action of digitalis in any way and may be used concurrently with this agent.

The effectiveness of hydroxyzine in long term use, that is, more than 4 months, has not been assessed by systematic clinical studies. The physician should reassess periodically the usefulness of the drug for the individual patient.

CONTRAINDICATIONS

Hydroxyzine hydrochloride intramuscular solution is intended only for intramuscular administration and should not, under any circumstances, be injected subcutaneously, intra-arterially, or intravenously.

This drug is contraindicated for patients who have shown a previous hypersensitivity to it.

Hydroxyzine, when administered to the pregnant mouse, rat, and rabbit, induced fetal abnormalities in the rat at doses substantially above the human therapeutic range. Clinical data in human beings are inadequate to establish safety in early pregnancy. Until such data are available, hydroxyzine is contraindicated in early pregnancy.

PRECAUTIONS

THE POTENTIATING ACTION OF HYDROXYZINE MUST BE CONSIDERED WHEN THE DRUG IS USED IN CONJUNCTION WITH CENTRAL NERVOUS SYSTEM DEPRESSANTS SUCH AS NARCOTICS, BARBITURATES, AND ALCOHOL. Rarely, cardiac arrests and death have been reported in association with the combined use of hydroxyzine hydrochloride IM and other CNS depressants. Therefore when central nervous system depressants are administered concomitantly with hydroxyzine their dosage should be reduced up to 50 per cent. The efficacy of hydroxy-zine as adjunctive pre- and postoperative sedative medication has also been well established, especially

as regards its ability to allay anxiety, control emesis, and reduce the amount of narcotic required.

HYDROXYZINE MAY POTENTIATE NARCOTICS AND BARBITURATES, so their use in preanesthetic adjunctive therapy should be modified on an individual basis. Atropine and other belladonna alkaloids are not affected by the drug.

When hydroxyzine is used preoperatively or prepartum, narcotic requirements may be reduced as much as 50 per cent. Thus, when 50 mg of VISTARIL (hydroxyzine hydrochloride) Intramuscular Solution is employed, meperidine dosage may be reduced from 100 mg to 50 mg. The administration of meperidine may result in severe hypotension in the postoperative patient or any individual whose ability to maintain blood pressure has been compromised by a depleted blood volume. Meperidine should be used with great caution and in reduced dosage in patients who are receiving other pre- and/or postoperative medications and in whom there is a risk of respiratory depression, hypotension, and profound sedation or coma occurring. Before using any medications concomitant with hydroxyzine, the manufacturer's prescribing information should be read carefully.

Since drowsiness may occur with the use of this drug, patients should be warned of this possibility and cautioned against driving a car or operating dangerous machinery while taking this drug.

As with all intramuscular preparations, VISTARIL Intramuscular Solution should be injected well within the body of a relatively large muscle. Inadvertent subcutaneous injection may result in significant tissue damage.

ADULTS: The preferred site is the upper outer quadrant of the buttock, (i.e., gluteus maximus), or the mid-lateral thigh.

CHILDREN: It is recommended that intramuscular injections be given preferably in the mid-lateral muscles of the thigh. In infants and small children the periphery of the upper outer quadrant of the gluteal region should be used only when necessary, such as in burn patients, in order to minimize the possibility of damage to the sciatic nerve.

The deltoid area should be used only if well developed such as in certain adults and older children, and then only with caution to avoid radial nerve injury. Intramuscular injections should not be made into the lower and mid-third of the upper arm. As with all intramuscular injections, aspiration is necessary to help avoid inadvertent injection into a blood vessel.

Geriatric Use: A determination has not been made whether controlled clinical studies of VISTARIL included sufficient numbers of subjects aged 65 and over to define a difference in response from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

The extent of renal excretion of VISTARIL has not been determined. Because elderly patients are more likely to have decreased renal function, care should be taken is dose selections.

Sedating drugs may cause confusion and over sedation in the elderly; elderly patients generally should be started on low doses of VISTARIL and observed closely.

ADVERSE REACTIONS

Therapeutic doses of hydroxyzine seldom produce impairment of mental alertness. However, drowsiness may occur; if so, it is usually transitory and may disappear in a few days of continued therapy or upon reduction of the dose. Dryness of the mouth may be encountered at higher doses. Extensive clinical use has substantiated the absence of toxic effects on the liver or bone marrow when administered in the recommended doses for over four years of uninterrupted therapy. The absence of adverse effects has been further demonstrated in experimental studies in which excessively high doses were administered.

Involuntary motor activity, including rare instances of tremor and convulsions, has been reported, usually with doses considerably higher than those recommended. Continuous therapy with over one gram per day has been employed in some patients without these effects having been encountered.

DOSAGE AND ADMINISTRATION

The recommended dosages for VISTARIL (hydroxyzine hydrochloride) Intramuscular Solution are:

For adult psychiatric and emotional emergencies, including acute alcoholism.	IM: 50-100 mg stat., and q. 4-6h., p.r.n.
Nausea and vomiting excluding nausea and vomiting of pregnancy.	Adults: 25-100 mg IM Children: 0.5 mg/lb body weight IM
Pre- and postoperaive adjunctive medication.	Adults: 25-100 mg IM Children: 0.5 mg/lb body weight IM
Pre- and postpartum adjunctive therapy.	25-100 mg IM

As with all potent medications, the dosage should be adjusted according to the patient's response to therapy.

FOR ADDITIONAL INFORMATION OF THE ADMINISTRATION AND SITE OF SELECTION SEE PRECAUTIONS SECTION. NOTE: VISTARIL (hydroxyzine hydrochloride) Intramuscular Solution may be administered without further dilution.

Patients may be started on intramuscular therapy when indicated. They should be maintained on oral therapy whenever this route is practicable.

HOW SUPPLIED

VISTARIL (hydroxyzine hydrochloride) Intramuscular Solution

Multi-Dose Vials

25 mg/mL: 10 mL vials (NDC 0049-5450-74)

50 mg/mL: 10 mL vials (NDC 0049-5460-74)

Unit Dose Vials

50 mg/mL-1 mL fill: packages of 25 vials (NDC 0049- 5462-76)

100 mg/2 mL-2 mL fill: packages of 25 vials (NDC 0049-5460-76)

STORAGE

Store below 86° F (30 ° C).

Protect from freezing.

FORMULA

Dosage Strength	**25 mg/1 mL**	**50 mg/1 mL 100 mg/2 mL**
Hydroxyzine hydrochloride	25 mg/mL	50 mg/mL
Benzyl Alcohol	0.9%	0.9%
Sodium hydroxide	to adjust to optimum pH	

ATARAX®

hydroxyzine hydrochloride

TABLETS AND SYRUP

DESCRIPTION

Hydroxyzine hydrochloride is designated chemically as 1-(p-chlorobenzhydryl) 4-[2-(2-hydroxyethoxy)-ethyl] piperazine dihydrochloride.

Inert ingredients for the tablets are: acacia; carnauba wax; dibasic calcium phosphate; gelatin; lactose; magnesium stearate; precipitated calcium carbonate; shellac; sucrose; talc; white wax. The 10 mg tablets also contain: sodium hydroxide; starch; titanium dioxide; Yellow 6 Lake. The 25 mg tablets also contain: starch, velo dark green. The 50 mg tablets also contain: starch; velo yellow. The 100 mg tablets also contain: alginic acid; Blue 1; polyethylene glycol; Red 3.

The inert ingredients for the syrup are: alcohol; menthol; peppermint oil; sodium benzoate; spearmint oil; sucrose; water.

CLINICAL PHARMACOLOGY

Atarax is unrelated chemically to the phenothiazines, reserpine, meprobamate, or the benzodiazepines.

Atarax is not a cortical depressant, but its action may be due to a suppression of activity in certain key regions of the subcortical area of the central nervous system. Primary skeletal muscle relaxation has been demonstrated experimentally. Bronchodilator activity, and antihistaminic and analgesic effects have been demonstrated experimentally and confirmed clinically. An antiemetic effect, both by the apomorphine test and the veriloid test, has been demonstrated. Pharmacological and clinical studies indicate that hydroxyzine in therapeutic dosage does not increase gastric secretion or acidity and in most cases has mild antisecretory activity. Hydroxyzine is rapidly absorbed from the gastrointestinal tract and Atarax's clinical effects are usually noted within 15 to 30 minutes after oral administration.

INDICATIONS

For symptomatic relief of anxiety and tension associated with psychoneurosis and as an adjunct in organic disease states in which anxiety is manifested.

Useful in the management of pruritus due to allergic conditions such as chronic urticaria and atopic and contact dermatoses, and in histamine-mediated pruritus.

As a sedative when used as premedication and following general anesthesia, **Hydroxyzine may potentiate meperidine (Demerol®) and barbiturates,** so their use in pre-anesthetic adjunctive therapy should be modified on an individual basis. Atropine and other belladonna alkaloids are not affected by the drug. Hydroxyzine is not known to interfere with the action of digitalis in any way and it may be used concurrently with this agent.

The effectiveness of hydroxyzine as an antianxiety agent for long term use, that is more than 4 months, has not been assessed by systematic clinical studies. The physician should reassess periodically the usefulness of the drug for the individual patient.

CONTRAINDICATIONS

Hydroxyzine, when administered to the pregnant mouse, rat, and rabbit, induced fetal abnormalities in the rat and mouse at doses substantially above the human therapeutic range. Clinical data in human beings are inadequate to establish safety in early pregnancy. Until such data are available, hydroxyzine is contraindicated in early pregnancy.

Hydroxyzine is contraindicated for patients who have shown a previous hypersensitivity to it.

WARNINGS

Nursing Mothers: It is not known whether this drug is excreted in human milk. Since many drugs are so excreted, hydroxyzine should not be given to nursing mothers.

For Tablets Only: This product is manufactured with 1,1,1-trichloroethane, a substance which harms public health and the environment by destroying ozone in the upper atmosphere.

PRECAUTIONS

THE POTENTIATING ACTION OF HYDROXYZINE MUST BE CONSIDERED WHEN THE DRUG IS USED IN CONJUNCTION WITH CENTRAL NERVOUS SYSTEM DEPRESSANTS SUCH AS NARCOTICS, NON-NARCOTIC ANALGESICS AND BARBITURATES. Therefore when central nervous system depressants are administered concomitantly with hydroxyzine their dosage should be reduced.

Since drowsiness may occur with use of this drug, patients should be warned of this possibility and cautioned against driving a car or operating dangerous machinery while taking Atarax. Patients should be advised against the simultaneous use of other CNS depressant drugs, and cautioned that the effect of alcohol may be increased.

Geriatric Use: A determination has not been made whether controlled clinical studies of ATARAX included sufficient numbers of subjects aged 65 and over to define a difference in response from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

The extent of renal excretion of ATARAX has not been determined. Because elderly patients are more likely to have decreased renal function, care should be taken is dose selections.

Sedating drugs may cause confusion and over sedation in the elderly; elderly patients generally should be started on low doses of ATARAX and observed closely.

ADVERSE REACTIONS

Side effects reported with the administration of Atarax (hydroxyzine hydrochloride) are usually mild and transitory in nature.

Anticholinergic: Dry mouth.

Central Nervous System: Drowsiness is usually transitory and may disappear in a few days of continued therapy or upon reduction of the dose. Involuntary motor activity including rare instances of tremor and convulsions have been reported, usually with doses considerably higher than those recommended. Clinically significant respiratory depression has not been reported at recommended doses.

OVERDOSAGE

The most common manifestation of Atarax overdosage is hypersedation. As in the management of overdosage with any drug, it should be borne in mind that multiple agents may have been taken.

If vomiting has not occurred spontaneously, it should be induced. Immediate gastric lavage is also recommended. General supportive care, including frequent monitoring of the vital signs and close observation of the patient, is indicated. Hypotension, though unlikely, may be controlled with intravenous fluids and Levophed® (levarterenol), or Aramine® (metaraminol). Do not use epinephrine as Atarax counteracts its pressor action.

There is no specific antidote. It is doubtful that hemodialysis would be of any value in the treatment of overdosage with hydroxyzine. However, if other agents such as barbiturates have been ingested concomitantly, hemodialysis may be indicated. There is no practical method to quantitate hydroxyzine in body fluids or tissue after its ingestion or administration.

DOSAGE

For symptomatic relief of anxiety and tension associated with psychoneurosis and as an adjunct in organic disease states in which anxiety is manifested: in adults, 50-100 mg q.i.d.; children under 6 years, 50 mg daily in divided doses and over 6 years, 50-100 mg daily in divided doses.

For use in the management of pruritus due to allergic conditions such as chronic urticaria and atopic and contact dermatoses, and in histamine-mediated pruritus: in adults, 25 mg t.i.d. or q.i.d.; children under 6 years, 50 mg daily in divided doses and over 6 years, 50-100 mg daily in divided doses.

As a sedative when used as a premedication and following general anesthesia: 50-100 mg in adults, and 0.6 mg/kg in children.

When treatment is initiated by the intramuscular route of administration, subsequent doses may be administered orally.

As with all medications, the dosage should be adjusted according to the patient's response to therapy.

SUPPLY

Atarax Tablets

10 mg--orange tablets: 100's (NDC 0049-5600-66), 500's (NDC 0049-5600-73) Unit Dose 10 × 10's (NDC 0049-5600-41), and Unit of Use 40's (NDC 0049-5600-43)

25 mg--green tablets: 100's (NDC 0049-5610-66), 500's (NDC 0049-5610-73) Unit Dose 10 × 10's (NDC 0049-5610-41), and Unit of Use 40's (NDC 0049-5610-43)

50 mg--yellow tablets: 100's (NDC 0049-5620-66), 500's (NDC 0049-5620-73) and Unit Dose 10 × 10's (NDC 0049-5620-41)

100 mg--red tablets: 100's (NDC 0049-5630-66) and Unit Dose 10 × 10's (NDC 0049-5630-41)

Atarax Syrup

10 mg per teaspoon (5 ml): 1 pint bottles (NDC 0049-5590-93)

Alcohol Content--Ethyl Alcohol--0.5% v/v

BIBLIOGRAPHY

Available on request.